used to determine pacemaker function or pacemaker battery function by periodically monitoring an implanted pacemaker's pulse rate and pulse width. The device is noninvasive, and it detects pacemaker pulse rate and width via external electrodes in contact with the patient's skin.

(b) *Classification.* Class II (performance standards).

§ 870.3650 Pacemaker polymeric mesh bag.

(a) *Identification.* A pacemaker polymeric mesh bag is an implanted device used to hold a pacemaker pulse generator. The bag is designed to create a stable implant environment for the pulse generator.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.3670 Pacemaker charger.

(a) *Identification.* A pacemaker charger is a device used transcutaneously to recharge the batteries of a rechargeable pacemaker.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.3680 Cardiovascular permanent or temporary pacemaker electrode.

(a) *Temporary pacemaker electrode*—(1) *Identification.* A temporary pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an *external* pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

(2) *Classification.* Class II (performance standards).

(b) *Permanent pacemaker electrode*—(1) *Identification.* A permanent pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an implantable pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

(2) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 870.3.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

§ 870.3690 Pacemaker test magnet.

(a) *Identification.* A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907-7971, Feb. 5, 1980, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

§ 870.3700 Pacemaker programmers.

(a) *Identification.* A pacemaker programmer is a device used to change noninvasively one or more of the electrical operating characteristics of a pacemaker.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

§ 870.3710 Pacemaker repair or replacement material.

(a) *Identification.* A pacemaker repair or replacement material is an adhesive, a sealant, a screw, a crimp, or any

other material used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987]

§ 870.3720 Pacemaker electrode function tester.

(a) *Identification.* A pacemaker electrode function tester is a device which is connected to an implanted pacemaker lead that supplies an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential.

(b) *Classification.* Class II (performance standards).

§ 870.3730 Pacemaker service tools.

(a) *Identification.* Pacemaker service tools are devices such as screwdrivers and Allen wrenches, used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker generator.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 54 FR 25049, June 12, 1989; 66 FR 38797, July 25, 2001]

§ 870.3800 Annuloplasty ring.

(a) *Identification.* An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Guidance for Annuloplasty Rings 510(k) Submissions.''

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.3850 Carotid sinus nerve stimulator.

(a) *Identification.* A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a carotid sinus nerve stimulator that was in commercial distribution before May 28, 1976. Any other carotid sinus nerve stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 52 FR 17736, May 11, 1987; 61 FR 50706, Sept. 27, 1996]

§ 870.3925 Replacement heart valve.

(a) *Identification.* A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 9, 1987 for any replacement heart valve that was in commercial distribution before May 28, 1976, or that has on or before December 9, 1987 been found to be substantially equivalent to a replacement heart valve that was in commercial distribution before May 28, 1976. Any other replacement heart valve shall have an approved PMA or a declared